

Date of Approval: DEC 17 2004

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-386

Levamisole Hydrochloride Soluble Drench Powder

Anthelmintic for cattle and sheep

Levamisole Hydrochloride Soluble Drench Powder used to make a drench solution for oral administration to cattle and sheep which is effective against various internal parasites.

Sponsored by:

Phoenix Scientific, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-386
- b. Sponsor: Phoenix Scientific, Inc.
3915 South 48th St. Terrace
St. Joseph, MO 64503

Drug Labeler Code: 059130
- c. Established Name: Levamisole hydrochloride
- d. Proprietary Name: Levamisole Hydrochloride Soluble Drench Powder
- e. Dosage Form: Soluble powder
- f. How Supplied: 1.8 oz (52 g) preprinted pouch
14.21 oz (403 g) bottle, water fill line indicated on label
21.34 oz (605 g) bottle, water fill line indicated on label
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 1.8 oz (52 g) preprinted pouch contains 46.8 grams of Levamisole hydrochloride activity
14.21 oz (403 g) bottle contains 362.7 grams of Levamisole hydrochloride activity
21.34 oz (605 g) bottle contains 544.5 grams of Levamisole hydrochloride activity
- i. Route of Administration: Oral
- j. Species/Class: Cattle and sheep
- k. Recommended Dosage: 8 milligrams per kilogram (mg/kg) body weight as a drench,
Cattle - Give 2 mL (milliliter) per 100 lb body weight.
Sheep- Give 2 mL (milliliter) per 50 lb body weight
- l. Pharmacological Category: Anthelmintic

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Levamisole Hydrochloride Soluble Drench Powder. The generic product is administered orally in drinking water, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product LEVASOLE (Levamisole hydrochloride) Soluble Drench Powder, the subject of Schering-Plough Animal Health Corp., NADA 112-051, was approved on December 23, 2003.

3. HUMAN SAFETY:

- **Tolerance**

The tolerance established for the pioneer product applies to the generic product. A tolerance of 0.1 part per million is established for negligible residues of Levamisole hydrochloride in the edible tissues of cattle, sheep, and swine (21 CFR 556.350).

- **Withdrawal Times**

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, April 9, 2001, the withdrawal times are those previously assigned to the pioneer product. The withdrawal times for Levamisole Hydrochloride Soluble Drench Powder is established for cattle, 48 hours prior to slaughter (21 CFR 520.1242a(e)(1)(iii)). In sheep the withdrawal time established is 72 hours prior to slaughter (21 CFR 520.1242a(e)(2)(iii)).

- **Regulatory Method for Residues**

A regulatory method is not required because one was not required for the pioneer products.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Levamisole Hydrochloride Soluble Drench Powder, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-386:

m. Indications:

Levamisole hydrochloride is a broad spectrum anthelmintic and is effective against the following adult nematode infections in cattle and sheep:

SHEEP:

Stomach Worms: *Haemonchus contortus*,
Trichostrongylus axei, *Teladorsagia circumcincta*.

Intestinal Worms: *Trichostrongylus colubriformis*,
Cooperia curticei, *Nematodirus spathiger*,
Bunostomum trigonocephalum, *Oesophagostomum columbianum*, *Chabertia ovina*

Lungworms: *Dictyocaulus filaria*

CATTLE:

Stomach Worms: *Haemonchus placei*, *Ostertagia ostertagi*, *Trichostrongylus axei*

Intestinal Worms: *Trichostrongylus longispicularis*, *Cooperia oncophora*, *Cooperia punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*

Lungworms: *Dictyocaulus viviparus*

n. Pioneer Product:

LEVASOLE Soluble Drench Powder; Levamisole hydrochloride; NADA 112-051; Schering-Plough Animal Health Corp.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA Sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTA Policy Letter; Bioequivalence Guideline, October 2002).

Levamisole Hydrochloride Drench Powder;

1.8 oz (52 g) preprinted pouch

14.21 oz (403 g) bottle, water fill line indicated on label

21.34 oz (605 g) bottle, water fill line indicated on label

Pioneer Labeling for NADA 112-051:

LEVASOLE Soluble Drench Powder;

21.34 oz (605 g) preprinted pouch

1.8 oz (52 g) preprinted pouch

DOSAGE AND ADMINISTRATION: When you are ready to deworm your cattle or sheep, add water to the powder in this bottle up to the 3 liter mark. Swirl to mix thoroughly before using. If any solution is left over it may be stored for up to 3 months in this tightly capped bottle. Shake well before using.

DATE WATER
WAS ADDED

TO THIS BOTTLE Month Day Year

Administer as a single drench dose as follows:

CATTLE - 2 mL per 100 lb body weight

Weight	Drench	Will Treat
100 lb	2 mL	1,500 head
300 lb	6 mL	500 head
500 lb	10 mL	300 head
700 lb	14 mL	214 head
1,000 lb	20 mL	150 head

SHEEP - 1 mL per 50 lb body weight

Weight	Drench	Will Treat
50 lb	1 mL	3,000 head
100 lb	2 mL	1,500 head
150 lb	3 mL	1,000 head
200 lb	4 mL	750 head

NOTE: Careful weight estimates are essential for proper performance of this product. Cattle and sheep maintained under conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment.

Manufactured By
Phoenix Scientific, Inc.
St. Joseph, MO 64503



NDC 59130-750-68

Levamisole Hydrochloride Soluble Drench Powder Anthelmintic

Cattle and Sheep Dewormer For Oral Use

This bottle contains 544.5 grams of levamisole hydrochloride activity.

INDICATIONS: Levamisole Hydrochloride is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

SHEEP: STOMACH WORMS: (*Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*), **INTESTINAL WORMS:** (*Trichostrongylus colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*), **LUNGWORMS:** (*Dictyocaulus filaria*).

CATTLE: STOMACH WORMS: (*Haemonchus placei*, *Trichostrongylus axei*, *Ostertagia ostertagi*), **INTESTINAL WORMS:** (*Trichostrongylus longispicularis*, *Cooperia oncophora*, *Cooperia punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*), **LUNGWORMS:** (*Dictyocaulus viviparus*).

WARNING: Keep out of reach of children.

ANADA 200-328, Approved by FDA

Net Wt. 21.34 oz (1.3 lb) (605 g)

AmTech®
Group, Inc.

WARNING: Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

CAUTION: Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Store between 15° and 30°C (59° and 86°F).

800510

Iss. 3-04



Lot No.

Exp. Date

DOSAGE AND ADMINISTRATION: When you are ready to deworm your cattle or sheep, add water to the powder in this bottle up to the line indicated on the side of this label. Swirl to mix thoroughly before using. If any solution is left over it may be stored for up to 3 months in this tightly capped bottle. Shake well before using.

DATE WATER
WAS ADDED

TO THIS BOTTLE Month Day Year

Administer as a single drench dose as follows:

CATTLE - 2 mL per 100 lb body weight

Weight	Drench Dosage	Bottle Will Treat
100 lb	2 mL	1000 head
300 lb	6 mL	333 head
500 lb	10 mL	200 head
700 lb	14 mL	142 head
1,000 lb	20 mL	100 head

SHEEP - 1 mL per 50 lb body weight

Weight	Drench Dosage	Bottle Will Treat
50 lb	1 mL	2000 head
100 lb	2 mL	1000 head
150 lb	3 mL	666 head
200 lb	4 mL	500 head

NOTE: Careful weight estimates are essential for proper performance of this product.

Cattle and sheep maintained under conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment.

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503



NDC 59130-750-69

Levamisole Hydrochloride Soluble Drench Powder Anthelmintic

Cattle and Sheep Dewormer For Oral Use

This bottle contains 362.7 grams of levamisole hydrochloride activity.

INDICATIONS: Levamisole Hydrochloride is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

SHEEP: STOMACH WORMS: (*Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*), **INTESTINAL WORMS:** (*Trichostrongylus colubriformis*, *Cooperia curdiei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*), **LUNGWORMS:** (*Dictyocaulus filaria*).

CATTLE: STOMACH WORMS: (*Haemonchus placei*, *Trichostrongylus axei*, *Ostertagia ostertagi*), **INTESTINAL WORMS:** (*Trichostrongylus longispicularis*, *Cooperia oncophora*, *Cooperia punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*), **LUNGWORMS:** (*Dictyocaulus viviparus*).

WARNING: Keep out of reach of children.
ANADA 200-386, Approved by FDA

Net Wt. 14.21 oz (0.87 lb) (403 g)

AmTech®
Group, Inc.

WARNING: Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Store between 15° and 30°C (59° and 86°F).

Fill with water to this line

2 3/16" from bottom

CAUTION: Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

800510

Iss. 3-04

Lot No.

Exp. Date



DOSAGE AND ADMINISTRATION

CATTLE-STANDARD DRENCH SOLUTION-

Place the contents of this packet in a 1 quart (32 fl oz) container, fill with water; swirl until dissolved. Administer as a single drench dose according to the following table:

Weight	Drench Dosage	Packet Will Treat
200 lb	1/2 fl oz	64 head
400 lb	1 fl oz	32 head
600 lb	1 1/2 fl oz	21 head
800 lb	2 fl oz	16 head

CONCENTRATED DRENCH SOLUTION-

For use with 20 mL Automatic Syringe. Place the contents of this packet in a standard household measuring container and add water to the 8 3/4 fl oz level. Swirl until dissolved. Give 2 mL (milliliter) per 100 lb body weight. Refer to the table above for the number of cattle this packet will treat.

SHEEP-STANDARD DRENCH SOLUTION-

Place the contents of this packet in a 1 gallon (128 fl oz) container, fill with water; swirl until dissolved. Administer as a single drench dose according to the following table:

Weight	Drench Dosage	Packet Will Treat
50 lb	1/2 fl oz	256 head
100 lb	1 fl oz	128 head
150 lb	1 1/2 fl oz	84 head
200 lb	2 fl oz	64 head

CONCENTRATED DRENCH SOLUTION-

For use with 20 mL Automatic Syringe. Place the contents of this packet in a standard household measuring container and add water to the 17 1/2 fl oz level. Swirl until dissolved. Give 2 mL per 50 lb body weight. Refer to the table above for the number of sheep this packet will treat.

NOTE: Careful weight estimates are essential for proper performance of this product. Prepare solutions as needed. However, excess solutions may be stored in clean closed containers up to 90 days without loss of anthelmintic activity.

Cattle and sheep maintained under conditions of constant helminth exposure may require treatment within 2 to 4 weeks after the first treatment.

WARNING: Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

CAUTION: Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Store between 15° and 30°C (59° and 86°F).

800510

Iss. 3-04

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

TAKE TIME



OBSERVE LABEL
DIRECTIONS



Lot No.

Exp. Date

NDC 59130-750-70

Levamisole Hydrochloride Soluble Drench Powder Anthelmintic

This packet contains 46.8 grams of levamisole hydrochloride activity.

Cattle and Sheep Dewormer For Oral Use

Administer as a standard drench with standard drench syringe or administer as a concentrated drench solution with an automatic drenching syringe.

INDICATIONS: Levamisole Hydrochloride is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

SHEEP: STOMACH WORMS: (*Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*), **INTESTINAL WORMS:** (*Trichostrongylus colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*), **LUNGWORMS:** (*Dictyocaulus filaria*).

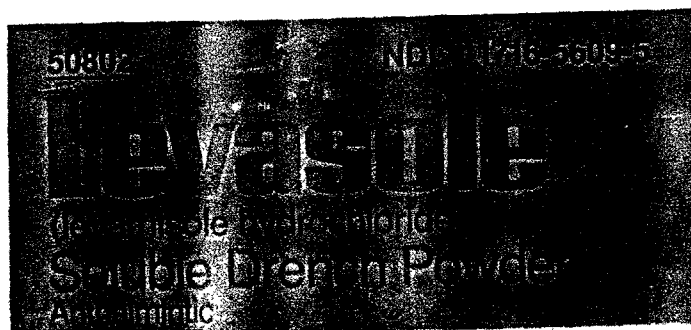
CATTLE: STOMACH WORMS: (*Haemonchus placei*, *Trichostrongylus axei*, *Ostertagia ostertagi*), **INTESTINAL WORMS:** (*Trichostrongylus longispicularis*, *Cooperia oncophora*, *Cooperia punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*), **LUNGWORMS:** (*Dictyocaulus viviparus*).

WARNING: Keep out of reach of children.

ANADA 200-386, Approved by FDA

Net Wt. 1.8 oz (52 g)

AmTech®
Group, Inc.



Each packet contains 46.8 grams of levamisole hydrochloride activity.

FOR ORAL USE IN CATTLE AND SHEEP

Administer as a standard drench with standard drench syringe or administer as a concentrated drench solution with an automatic drenching syringe.

RECOMMENDATIONS:

LEVASOLE (levamisole hydrochloride) is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

STOMACH WORMS: (*Haemonchus*, *Trichostrongylus*, *Ostertagia*)

INTESTINAL WORMS: (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*)
[*Chabertia*—sheep only]

LUNGWORMS: (*Dictyocaulus*)

WARNING: Keep out of reach of children.

MADE IN IRELAND

Net Wt. 1.8 oz. (52 g)

Pitman-Moore

Pitman-Moore, Inc.
Mundelein, IL 60060, U.S.A.



DOSAGE AND ADMINISTRATION

CATTLE—STANDARD DRENCH SOLUTION—Place the contents of this packet in a 1 quart (32 fl. oz.) container, fill with water; swirl until dissolved. Administer as a single drench dose according to the following table:

WEIGHT	DRENCH DOSAGE	PACKET WILL TREAT
200 lb.	½ fl. oz.	64 head
400 lb.	1 fl. oz.	32 head
600 lb.	1½ fl. oz.	21 head
800 lb.	2 fl. oz.	16 head

SHEEP—STANDARD DRENCH SOLUTION—Place the contents of this packet in a 1 gallon (128 fl. oz.) container, fill with water; swirl until dissolved. Administer as a single drench dose according to the following table:

WEIGHT	DRENCH DOSAGE	PACKET WILL TREAT
50 lb.	½ fl. oz.	256 head
100 lb.	1 fl. oz.	128 head
150 lb.	1½ fl. oz.	84 head
200 lb.	2 fl. oz.	64 head

CONCENTRATED DRENCH SOLUTION—For use with Cooper 20 ml Automatic Mark II Syringe. Place the contents of this packet in a standard household measuring container and add water to the 8¼ fl. oz. level; or use the measuring container available from your supplier and add water to the mark. Swirl until dissolved. Give 2 ml (milliliter) per 100 lb. body weight. Refer to the table above for the number of cattle this packet will treat.

CONCENTRATED DRENCH SOLUTION—For use with Cooper 20 ml Automatic Mark II Syringe. Place the contents of this packet in a standard household measuring container and add water to the 17½ fl. oz. level. Swirl until dissolved. Give 2 ml per 50 lb. body weight. Refer to the table above for the number of sheep this packet will treat.

NOTE: Careful weight estimates are essential for proper performance of this product. Prepare solutions as needed. However, excess solutions may be stored in clean closed containers up to 90 days without loss of anthelmintic activity.

Cattle and Sheep maintained under conditions of constant helminth exposure may require re-treatment within two to four weeks after the first treatment.

WARNING: Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

CAUTION: Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

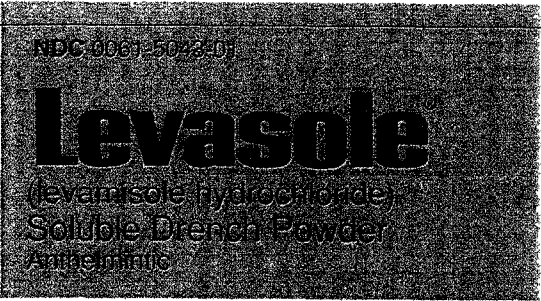
Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

© P-M 82

*Trademark

29987 PM4

7/30/03 • SPAH • LEVASOLE BOTTLE LABEL
00000000 • PCR# 00000 • 143mm x 127mm • OUTPUT BY AF



Cattle and Sheep Dewormer For Oral Use

This bottle contains 544.5 grams of levamisole hydrochloride activity.

INDICATIONS: LEVASOLE (levamisole hydrochloride) is a broad spectrum anthelmintic and is effective against the following adult nematode infections in cattle and sheep:

SHEEP:

STOMACH WORMS: *Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*.

INTESTINAL WORMS: *Trichostrongylus colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*.
LUNGWORMS: *Dictyocaulus filaria*.

CATTLE:

STOMACH WORMS: *Haemonchus placei*, *Trichostrongylus axei*, *Ostertagia ostertagi*.

INTESTINAL WORMS: *Trichostrongylus longispicularis*, *Cooperia oncophora*, *Cooperia punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*.

LUNGWORMS: *Dictyocaulus viviparus*.

TAKE TIME

OBSERVE LABEL

DIRECTIONS

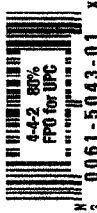
Net Wt. 21.34 oz (1.3 lb)
(605 g)



Schering-Plough Animal Health

Schering-Plough Animal Health Corp.
Union, NJ 07083
Made In Ireland

NADA #112-051, Approved by FDA.



DOSAGE AND ADMINISTRATION: When you are ready to deworm your cattle or sheep, add water to the powder in this bottle up to the 3 liter mark. Swirl to mix thoroughly before using. If any solution is left over it may be stored for up to 3 months in this tightly capped bottle. Shake well before using.

DATE WATER

WAS ADDED

TO THIS BOTTLE

Month

Day

Year

Administer as a single drench at a dose of 8 mg/kg body weight:

CATTLE – 2 mL per 100 lb body weight

Weight	Drench Dosage	Bottle Will Treat
100 lb	2 mL	1,500 head
300 lb	6 mL	500 head
500 lb	10 mL	300 head
700 lb	14 mL	214 head
1,000 lb	20 mL	150 head

SHEEP – 1 mL per 50 lb body weight

Weight	Drench Dosage	Bottle Will Treat
50 lb	1 mL	3,000 head
100 lb	2 mL	1,500 head
150 lb	3 mL	1,000 head
200 lb	4 mL	750 head

NOTE: Careful weight estimates are essential for proper performance of this product.

Cattle and sheep maintained under conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment.

WARNING: Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

CAUTION: Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Copyright © 1997, Schering-Plough Animal Health Corp.
All rights reserved. Product of Jensen Research 00000000 Rev 0/00

PACKAGING COMPONENT APPROVAL

SUBMISSION #

EXAMINE BLACK & WHITE COPY AND ACCOMPANYING COLOR BREAK.

	APPROVED	NOT APPROVED	DATE
DESIGNER _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
COPY EDITOR _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
MEDICAL _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
TRADEMARKS _____	<input type="checkbox"/>	<input type="checkbox"/>	_____

IE COLORS